USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network



Voluntary _ Public

**Date:** 4/19/2011
**GAIN Report Number:**

# Peru

**Post:** Lima

# Peru Approves Biosafety Regulation

**Report Categories:**
Biotechnology
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**Report Highlights:**
Peru approves the Agricultural Biosafety Regulation. On April 15, the government of Peru (GOP) published Supreme Decree 003-2011-AG which regulates research, production and trade of genetically modified (GM) products. The Agricultural Biosafety Regulation appoints the National Agricultural Innovation Institute (INIA) as the lead agency for regulating agricultural biotechnology issues.

## General Information:

Peru approves the Agricultural Biosafety Regulation. On April 15, the government of Peru (GOP) published Supreme Decree 003-2011-AG which regulates research, production and trade of genetically modified (GM) products. This is an excellent news for Peruvian agricultural producers who are finally able to benefit from this technology to increase their productivity, lower their cost, improve environmental standards and finally be more competitive.

The Agricultural Biosafety Regulation appoints the National Agricultural Innovation Institute (INIA) as the lead agency for regulating agricultural biotechnology issues. It also establishes a technical working group that includes members from INIA, the Ministry of Environment, Ministry of Agriculture, the Peruvian SPS agency (SENASA) and academia. The technical working group will be responsible for conducting the risk assessment prior to approving a GM application.

The following is a summary of the Peruvian Biosafety Rules for the Agriculture or Forestry Sectors. The original version in Spanish can be found at: http://www.inia.gob.pe/eventos/evento0694/default.htm

Biosafety Rules for the Agriculture or Forestry Sectors

Title I: General Provisions

Chapter I: Object and Definitions

This document refers to the Cartagena Protocol and previous regulations. Regulations are established for genetically modified organisms (GMOs) in the agricultural or forestry sector and for products derived from GMOs. Specific objectives include regulating procedures for the authorization of research and production of GMOs and for their use in agricultural and forest systems, as well as establishing risk evaluations.

Chapter II: Scope of Application

This regulation applies to any domestic or foreign individuals and corporations seeking to use GMOs in Peruvian territory. GMOs of agricultural and forestry origin include those used for food, feed or processing, or are used for field release.

Title II: Functions and Powers of Sectorial Bodies

Chapter I: Competence

This regulation refers to INIA as the regulating agency for genetically modified products of agricultural or forestry origin. INIA has the function and power established in this law.

Chapter II: Sectorial Technical Group

The Sectorial Technical Group (GTS) is the support branch of INIA, responsible for the technical evaluation, risk and management of activities related to GMOs. GTS is also representative of the Ministry of the Environment, the Director of Environmental Affairs, SENASA (Peru's SPS group), and environmental experts (including

universities).

Title III: The Authorization of Uses and Activities with GMOs

Chapter I: Procedure

Registration of GMOs will begin with the person or company who wishes to use biotechnology. The person should submit required information to GTS, including a description of the agricultural/forestry GMO, purposes of any activities planned for the GMO, etc. Additionally, a risk evaluation should be performed by STG, after which an opinion will be given by INIA whether the GMO can be registered for use, as well as its possible risk to human health and biological diversity.

Chapter II: Rules for the Treatment of Confidential Information

INIA will give confidential treatment to GMOs prior to the risk assessment.

Chapter III: Risk Evaluation

The application must include information on any other applications submitted to other countries. If a decision was reached on the GMO, then the results must be included in the application. A background check will be completed on each GMO. If the product is found to have been rejected or is being researched in another country, then it will be automatically rejected by INIA. The risk evaluation will be performed based upon the information on the GMO given in the application, as well as on scientific and technical procedures. The evaluation process will include identifying the new genetic or phenotypic characteristic in the GMO which may have adverse effects on biological diversity and human health. The level of risk that these new attributes have will be evaluated and assessed, based upon the chance that these risks actually occur. Measures and emergency procedures will be developed to manage these risks. If it is necessary for the risk evaluation, INIA may ask assistance from experts. The acceptance of a GMO will include descriptions of the required labeling, packaging, handling and transport of the products.

Chapter IV: Risk Management

A Biosafety Quality Certificate (CCB) allows for persons to use research stations owned by INIA to run pilots on GMOs before commercializing the products. These persons must have internal regulations and protocols for biosafety, and these rules must be submitted to INIA for revision.

Chapter V: Internal Biosecurity Committees (ClBio)

Groups working with agricultural or forestry-related GMOs must appoint an Internal Biosecurity Committee (ClBio). The ClBio must contain a specialist in biology and the social and economic aspects of GMOs, and must submit an annual report to INIA. Additionally, the ClBio must establish rules and internal control mechanisms, based upon technical standards issued by INIA. The responsibilities of IBC include granting proposals for agricultural and forestry-focused GMOs, addressing risks and possible mitigation steps, and submitting necessary documentation to INIA.

Chapter VI: Biosecurity Quality Certificate (CCB)

Any parties interested in developing biotechnology projects must apply for the biosecurity quality certificate from INIA, to insure that the environment used to develop projects is secure. INIA has thirty (30) working days to issue the documentation to interested companies. INIA has the right to send inspectors to for unannounced visits, to ensure that the infrastructure and technical conditions are being abided by.

Chapter VII: Contained Use of GMOs

This regulation applies to the research, production, and quality control of agricultural and forestry-related GMOs. Additionally, non-modified organisms should be grown in the same environment as the GMOs.

Chapter VIII: Levels of Biosecurity

The level of biosecurity of an experiment should be based upon the risk level of the GMOs involved. Hazard levels of a GMO are separated into four classes, with increasing levels of risk. The lowest hazard level is applied to plants that historically do not cause disease in humans or cross-breed with weeds or other plants. Hazard levels increase as plants are able to cross-breed with wild species and/or infectious agents may be created, resulting in pathogenic agents.

Chapter IX: Registry of People or Companies Engaged in Activities using GMOs

Any person or company who wants to work with agricultural or forestry-related GMOs must register with INIA before beginning any project.

Chapter X: Emergency Plans

Inspectors who detect an unauthorized project or find problems with an activity regarding GMOs should give immediate notice to INIA, and enact an emergency plan. Emergency plans should be presented to the STG as part of the technical information included in the risk evaluation. Plans should include possible risks, as well as remediation steps that should be taken in case of emergency.

<u>Title IV: Control of Movement of GMOs</u>

Chapter I: Control of Importation and International Movement of GMOs

If a company wishes to import agricultural or forestry-based GMOs, SENASA requires an Animal or Plant Sanitation Certificate, given by STG- INIA. SENASA will inspect GMOs at transit locations to ensure compliance with the law.

Chapter II: Control of Exportation of GMOs

GMOs of agricultural and/or forest origin must have export permits issued by the proper authority. Chapter II lists the proper authorities for each type of GMO export. Additionally for exportation to occur, permission must be given from the host country and INIA.

Chapter III: Transport, Packaging and Labeling of GMOs

Packaging, transport, and labeling for GMOs is dependent upon the risk assessment provided for each product. INIA may request assistance from the National Commission of Biodiversity (CONABID) and INDECOPI.

Title V: Surveillance

INIA and IIAP will monitor, provide surveillance, and control the facilities working with GMOs. SENASA will track the importation and exportation of GMOs from the country.

Title VI: Methods of Information Exchange

INIA and STG should exchange information regarding GMOs, including complaints, technical information, risk assessments and license reevaluations. Additionally, INIA and the Ministry of the Environment (MINAM) must exchange registries of activities related to GMOs, as well as concessions and permits granted to agricultural and forestry-related activities.

Title VII: Processing

Services fulfilled by INIA and SENASA are subject to payment.

Title VIII: Infractions and Sanctions

Failure to comply with the provisions listed in the internal biosecurity regulation will result in criminal penalties. Examples of infractions include planting GMOs outside of approved areas, unauthorized release of products, submitting false information about activities, and improperly monitoring GMOs. The aforementioned activities may result in suspension and cancellation of permits and licenses, confiscation of property, and closure of facilities.